PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 542430C	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001073	International filing date *(day/month/year)* 12 August 2004	Priority date *(day/month/year)* 12 August 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A61M 1/12

Applicant

HEART ASSIST TECHNOLOGIES PTY LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
10 March 2005	11 July 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **MANO RAMACHANDRAN** Telephone No. (02) 6283 2166

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001073

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☒ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **6-22**	**YES**
	Claims **1-5**	**NO**
Inventive step (IS)	Claims **6-22**	**YES**
	Claims **1-5**	**NO**
Industrial applicability (IA)	Claims **1-22**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

NOVELTY (N) AND INVENTIVE STEP (IS) Claims 6-22:

None of the citations listed in the ISR discloses a method of treating a failing heart/an implantable direct cardiac compression system including a left implantable direct cardiac compression device and a right implantable direct cardiac compression device, each said device having a body with a flexible frontal compression wall adapted to be affixed to a corresponding ventricle and to compress the ventricle upon pressurisation and a rear wall stiffer than the compression wall, wherein
either the body of the left implantable direct cardiac compression device has two flexible flaps extending from a respective lateral side of the body
or the body of the right implantable direct cardiac compression device has at least one strap extending from a respective lateral side
to secure the respective device to the corresponding ventricle.

Hence the invention claimed in claims 6-22 is considered to be novel and involves an inventive step.

NOVELTY (N) claims 1-5:

Claims 1,2:

(a) WO 199855165 A (WOODARD et al)

(b) WO 200036995 A (CORSET INC)

(c) US 5800334 A (WILK)

Each of these citations (a)-(c) discloses an implantable cardiac compression device having a pressurisable chamber formed of a flexible front wall and a rear wall , two flexible flaps extending from the lateral sides, the front wall and the flaps have a surface layer formed of a biointegratable material as claimed in claims 1,2. See for example in citation (a): page 40, lines 14-27, figures 11,12,14.

Claims 3-5:

Each of the citations (a) and (b) discloses the additional features of claims 3-5. See for example in citation (a): page 40, line 14-page 42, line 2, figures 11, 12, 14.

Hence the invention claimed in claims 1-5 is not considered to be novel.

INVENTIVE STEP (IS) claims 1-5:

Claims 1-5 as above

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Independent claims 1, 6, 9 and 18 do not define the invention because these claims do not define all the essential features of the invention.

Claim 1 defines only one implantable direct cardiac compression device with two flexible flaps.
Claim 6 defines two implantable direct cardiac compression devices where one of the devices has two flexible flaps.
Claims 9 and 18 define two implantable direct cardiac compression devices where one of the devices has at least one strap.
It appears that the invention is directed to the features of claims 6 and 9 or claims 6 and 18.